

 CHA Cambridge Health Alliance	INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH
<p>We try to make this form easy to understand, but it may have words or ideas that are not clear to you. Please ask the study doctor or study staff to explain anything you do not understand. You may take this form home with you to discuss with family or friends before you decide whether to be in this study.</p>	
<p>Study Title: Effect of Mindfulness on Opioid Use and Anxiety During Primary Care Buprenorphine Treatment (MINDFUL-OBOT)</p>	
<p>Your name (Participant):</p>	<p>Today's Date:</p>
<p><u>Not including</u> this study, are you taking part in any research now? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>Name of Principal Investigator: Zev Schuman-Olivier, MD</p>	
<p>Name of Co-Investigator(s): Richa Gawande, PhD, Elaine Fredricksen, LICSW, Randi Sokol, MD, Alexandra Oxnard MD, Ellie Grossman, MD, Benjamin Cook, PhD, Todd Griswold, MD.</p>	
<p>Consent form version date or number: Version 1.5</p>	
<p>Name and telephone number of study contact to call with questions: Thomas Fatkin, Study Coordinator (617-806-8567, mindfulobot@challiance.org)</p>	
<p>CHA IRB Number: CHA-IRB-1094/08/18</p> <p>IRB Approval Date: May 15, 2019</p> <p>IRB Expiration Date: October 29, 2019</p>	<p>Study Sponsor(s): NIH</p>

Please read this form carefully. This form tells you about a pilot study called MINDFUL-OBOT. If you choose to take part in this study, you will be asked to sign this form. You will be given a copy of the signed form for your records.

If you have any questions about the research or about this form, please ask us.

Taking part in this study is voluntary. You have the choice to take part or not. If you take part in this study, you may leave at any time for any reason. If you don't want to take part, it does not change any part of the standard health care you will receive at Cambridge Health Alliance.

Introduction

Mindfulness is paying attention, on purpose, to the present moment in a non-judgmental way. Mindfulness practice can help people lower stress and feel less anxious and depressed. It can also increase feelings of well-being. Learning to be mindful requires regular practice. Regular practice has lasting effects on the brain. It can help you increase self-control and decrease craving for habits, such as tobacco smoking, overuse of alcohol, or prescription drugs. With just a few weeks of daily practice, many people can lower their daily stress and feel happier. This program aims to bring tools to CHA patients with opioid use disorder and who are currently receiving buprenorphine/naloxone treatment.

The National Institutes of Health (NIH) is providing funding for this research.

Purpose for the Study

This study will offer mindfulness training every week. The study will examine how mindfulness training affects your mood, your well-being, your drug use, and your ability to pay attention to external and internal experiences. Approximately 30 participants will be enrolled in this study between September 2018 and May 2019.

New Findings

We will tell you about any new findings that may cause you to change your mind about being in this study.

Reasons why you have been invited to be in this study

You have been invited to participate in this study because you are a patient at Cambridge Health Alliance (CHA) and are receiving a prescription of buprenorphine.

To take part in this study, you have to meet the following criteria:

- You are 18 years or older
- You have a diagnosis of opioid use disorder and be prescribed buprenorphine
- You understand English well enough to understand procedures and questionnaires and provide informed consent
- You are able to fill out weekly surveys on a computer at home, at the Malden Care Center, at the Revere Care Center the Central Street Care Center, or the Center for Mindfulness and Compassion
- You are not participating in another research study

Period of Participation (how long you will be in this study)

You will be screened during your first visit to determine whether you are eligible for this study. You will be compensated for this visit even if you are not eligible to join the study.

If you are found to be eligible after the in-person screening, you will complete a survey session at baseline, 4 and 24 weeks and participate in mindfulness group for at least 4 weeks with an option to continue for up to 6 months. You will come in person for a mindfulness group every week, which may substitute for standard group treatment requirements. At the beginning, after 4 weeks and after 24 weeks you will come in for an additional 1.5-hour session where you will complete surveys and computer tasks. You will also be invited to share about your experience in this study after the 4-week and 24-week visit.

We ask you NOT to participate if you expect to be hospitalized in the next 6 months for a health problem. We will ask you NOT to participate if you expect to go to jail in the next 6 months. In addition, we do not recommend enrollment in this program for women who are past their first trimester (week 13 or later) of pregnancy because they would be likely to go into labor before finishing the study. No other experimental treatments or participation in other investigational trials are allowed during the study.

Procedures (what will happen during this study)

This study has 5 components: mindfulness group sessions, surveys, urine toxicology testing, interviews, and computer tasks.

1) Mindfulness Group Sessions: You will be asked to attend a weekly mindfulness group for 60-75 minutes each week at your primary care center or at the Central Street Health Center. The groups are regular groups designed for people in early recovery where you can learn some mindfulness skills to help you reduce stress and anxiety, prevent relapse and the return of depression, and cope better with pain and cravings. Groups are billed to insurance like any other clinical group. At some point during the study, you will have the option of joining a more focused 8-week advanced mindfulness group which meets for 2 hours every week at the Central Street Health Center. The timing of this group for you will be subject to availability and scheduling. These mindfulness group sessions may substitute for standard group participation requirements for your buprenorphine treatment—discuss your individual treatment plan details with your providers.

2) Weekly Surveys: You will fill out weekly surveys that ask questions about your substance use in the past week. You will also fill out weekly surveys that track the amount of mindfulness practice you do at home every day (home practice will be encouraged -- *you are asked to try your best, but the practice is just time for you*).

3) Urine Toxicology Testing: You will participate in a urine toxicology test at least every 2 weeks as required by your clinical treatment team (*may also be weekly if required by your doctor*).

4) Interviews: You will be given the opportunity to share your experience during a one-on-one interview with a study staff member after week 4 and after week 24.

5) Computer Tasks and Longer Surveys: After you sign the informed consent form, you will participate in a 1.5-hour computer task session 3 times: at the beginning of the study, at 4 weeks, and at 24 weeks. Each visit will be conducted at the Center for Mindfulness and Compassion (CMC), the Central Street Care Center, or at your primary care clinic.

At these visits, you will do the following:

- On the computer, you will do:
 - **An attention task:** You will press a key on the keyboard based on numbers that appear on the screen. This task will be done on a study computer. (Duration: 25 minutes)
 - **A choice task:** You will choose between two different options given at different times. This task will be done on a study computer. (Duration: 1 minute)
- Fill out approximately 15 surveys on a computer or iPad, or on paper, for 45 minutes.
- You will be able to take a short break if needed during the survey session.

Electronic Medical Records:

We will collect data from your electronic medical records. This will be from the year before this study and up to 3 years after you start the study. This is to study the long-term effects of the mindfulness practice. We look at your prescribed medications and health information. This information includes medication names and dosages, blood pressure, height, weight, your health-related behaviors, your mood, and the visits that you made to the hospital and to your primary care provider. You can choose to leave the study and remove our access to your data at any time.

Participant Engagement Call (Every other week):

You will be called by a member of the study staff every other week during the study. This will be a short (5 minute) outreach call to provide you support as you participate in the study. During this call, the study staff can help you answer any questions, help you with any problems you may have in filling out the surveys, and hear about anything that you would like to share with the study staff. If you don't answer this phone call, the study staff will leave a message.

Graduation Ceremony

At the end of the study, all participants will be invited to attend an optional celebration that will involve a dinner and an opportunity to connect with other people you may have met during the study.

Possible Risks, Discomforts, Side Effects, and Inconveniences

The following are possible risks and side effects associated with your participation in this study:

- Some questions that you will be asked are personal. You might feel stressed or embarrassed. You may ask to see the questions before you participate in the study. If you get upset or stressed, you can call the research staff. The research coordinator can call your behavioral health provider if needed.
- You may spend extra time learning mindfulness techniques and doing study tasks.
- You may have physical discomfort from the gentle movement part of the training.
- You may feel anxious because of the difficulties in this mental training program.
- You might not benefit from this program.
- Despite strong efforts to maintain your confidentiality, your protected health information (PHI) might be exposed. All digital information collection and transfer using the internet carries the risk of loss of confidentiality due to privacy breach.
- Eye strain from performing computer tasks

We will be happy to answer any questions you have about these risks and/or side effects. Please talk with a study team member if you have any study-related questions or concerns.

Alternatives to Participation

Participation is **voluntary**. Whether or not you enroll in this study will not affect your health care at CHA.

Benefits (good that may come from being in this research)

Potential benefits to you from being in this study are:

- You may have less of a need for symptom-relieving medication like benzodiazepines and opioids
- You may find that you smoke fewer cigarettes and drink less alcohol
- You can learn skills for controlling behavior and improved well-being
- You may feel less depression, anxiety, panic, stress, and pain
- You may feel more joy and gratitude

Some of these benefits may not help you directly. However, what we learn from this research may help others in the future. There is no guarantee you will benefit from being in the study.

Costs

You will not have any additional costs from being in this study. The time related to study visits and procedures will be given to you at no cost. Costs for group treatment will be billed as usual to you or your insurance. Co-pays for group treatment will follow standard procedure for your insurance providers.

As with standard treatment, you will have to pay for your own transportation to attend weekly mindfulness sessions. The study team can provide up to \$10 to cover transportation costs for the 4-week and 24-week in-office study session with computer tasks. The study staff can work with your clinical treatment team to determine if transportation assistance can be provided for your clinical groups.

Payment

You will be paid up to \$186:

- \$20 for screening/consent visit
- \$20 for baseline surveys/computer task
- \$23 for weekly home practice diaries (\$1/each)
- \$23 for substance use weekly surveys
- \$20 at 4-week study visit
- Up to \$30 for interviews (\$15 for each of the two interviews)
- \$20 at 24-week study visit
- \$30 for a completion bonus at the end of the study. You will get this bonus if you have completed your baseline, 4-week, and 24-week study visit, and 75% of your urine testing visits and weekly surveys.

You will receive payments **4 times** during the study:

Payment 1: \$20 for Screening/Consent

Payment 2: \$20 at Baseline

Payment 3: Up to \$35 at your 4-week study visit

Payment 4: Up to \$111 at your 24-week study visit

You will receive a prepaid card that may be reloaded as the study progresses. Study staff will fill the card with the amount of your study payment after your baseline, week 4 and week 24 visits.

Study-Related Injury

If you get hurt or get sick as a direct result of being in this study, emergency treatment will be given to you. All needed emergency care is available to you, just as it is to the general public. Any needed medical care is available to you at the usual cost. You or your insurance carrier will have to pay for any such medical care.

Cambridge Health Alliance has not set aside any money to pay for a research-related injury or illness. There are no plans to pay for your treatment if you get hurt or sick as part of this study.

Voluntary Participation

Taking part in this study is voluntary. If you do not take part, you will not be punished or lose benefits that you have the right to receive. The quality of your medical care will be the same at Cambridge Health Alliance whether you take part in the study, refuse to take part, or decide to leave the study.

If you choose to take part and then decide to stop, tell a member of the research team. It may not be safe for you to suddenly stop being in this study. The study team will help you stop safely.

Any information collected from you before the date you leave the study will be used in the research study.

The research team may decide that you can no longer be in the study. This could be for several reasons, including:

1. You have had a bad reaction to the study.
2. You did not follow all the study rules.

Audio Recording of Group Sessions

Some group sessions during the course may be audio recorded. This is so that we can monitor the way the group leader leads each session. Audio will not be linked to any personal or identifying information. Please indicate your agreement to be audio-recorded during group sessions.

I agree to be audio recorded during group sessions.

☐ I agree

☐ I do not agree

Future Contact

Sometimes the study team has information about other studies or opportunities that might interest you. Please indicate below whether you give permission for us to contact you about future studies or opportunities via email or phone. We will retain your phone number and e-mail address in a separate database from the study database.

☐ I agree

☐ I do not agree

Privacy / Confidentiality

There are laws (state and national) that protect your health information to keep it private. We follow those laws. Your identity, medical records, and study data will be kept confidential, except as required by law. We will protect all of your health information, including your Protected Health Information or "PHI." Your PHI is any health information that identifies you. This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local proceeding. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project.

If you take part in this study, you agree to let the research team use your medical information. Do not take part in this study if you do not want the research team to access your health information.

We will follow these guides:

- The research team will view your health information from the year before you enrolled in the study. during the life of this study, and for three years after you finish the study.
- We will not include any information that could identify you in any publication.
- We will remove all of your identifiable information (name, address, telephone number, etc.) from the study database 7 years after the study has been completed.

We will make every effort to keep your information private, but we cannot guarantee it. The Cambridge Health Alliance Institutional Review Board (IRB) is responsible for protecting the safety and welfare of people who take part in research studies at our hospital. IRB staff may ask to look at any research records to make sure the study team is following the laws and rules to protect you. Certain government agencies, including the Office for Human Research Protections and the U.S. Food and Drug Administration (regulates drug and device studies), may also look at records that identify you.

Sometimes, we are required to share your study records with others, too, including:

- Other researchers conducting this study
- Research collaborators
- The study sponsor and any companies that the sponsor uses to oversee, manage, or conduct the study
- Clinical staff not involved in the study, but involved in your regular treatment
- Insurance companies.

If any of these groups ask to look at your information, then we cannot prevent it from being shared. Once information is shared, we cannot guarantee any further confidentiality and privacy.

- **Despite our best efforts to protect privacy and ensure confidentiality, data breaches can happen when you are using internet-based technology.**

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US Law. This Website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Period of Authorization

Your authorization on this research project will expire 10 years after completion of data gathering for the study. If you change your mind and want to withdraw your authorization please tell a member of the study team or write to the HIPAA Privacy Officer for Research, Cambridge Health Alliance, 1493 Cambridge Street, Cambridge, MA 02139. If you withdraw your authorization, you may no longer be allowed to participate in the study described in this form.

Getting Help (Contacts)

If you have questions about this study, please ask a member of the study team. Some questions people have:

- What are the risks and benefits of being in this study?
- What other choices are available?
- What are my rights as a research participant?
- What should I do if I feel pressured to take part in this study?
- How is my health information used in this study?
- How will my health information be protected?

Call or email the study investigators for answers to any study-related questions or if you get hurt or sick as a result of being in this study. This is how to contact us Monday to Friday during regular business hours:

The easiest way to reach the study team about study related questions is by email at mindfulobot@challiance.org.

You can also call study investigators if you have an urgent question or concern.

Zev Schuman-Olivier, MD (Principal Investigator)
Richa Gawande, PhD (Program Manager)

617-591-6055
 617-591-6429

If you have questions about your rights as a study participant, please contact either the IRB office or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30am until 5:00pm:

IRB Chair: Dr. Lior Givon
 Telephone: 617-499-8302

Patient Relations Manager: Lorraine Vendetti
 Telephone: 617-665-1398

Signature of Consent

I, the study participant, have read this form or it has been read to me. I understand my part in this study and have had my questions answered to my satisfaction. I agree to take part in this research study.

Participant's Signature

Date

I have informed the study participant, _____ of:
Participant's Printed Name

- The procedures, purpose, and risks related to participation in the above-described study;
- How his/her health information may be used, shared, and reported, and;
- His/her privacy rights.

The study participant has been provided with a signed copy of this form.

Signature of Researcher Obtaining Consent

Date

Printed Name of Researcher Obtaining Consent

Signature of Participant's Legally
Authorized Representative

Date

Printed name of Participant's Legally
Authorized Representative

Date

This form is valid only if it has the IRB stamp of approval.

